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EXAMINER	
ISSAC, ROY P	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/771,829	BINGAMAN ET AL.	
	Examiner	Art Unit	
	Roy P. Issac	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 2* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/17/04, 10/18/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application claims priority under 35 U.S.C § 119(e) to the provisional application, U.S. Patent Application Serial No.60/448,943 filed on February 20, 2003. Claims 1-2 are pending and are considered on the merits in this office action.

Claim Objections

Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 is a method for the treatment of retinal edema or non-proliferative diabetic retinopathy by the use of a glucocorticoid. Glucocorticoids are a class of steroids that are capable of binding the glucocorticoid receptor. Claim 2 depends from claim 1 and limits claim 1 by further comprising anecortave acetate. Anecortave acetate in itself is a glucocorticoid (X; Edelman et. al., PTO-892, Abstract cited by the examiner). Thus, claim 2 does not further limit claim 1. As such, claim 2 is an improper dependent claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 refers to a formulation "free of classical preservatives." The phrase "classical preservatives" is not clearly defined in the specification. In fact, all the embodiments in the specification include NaCl as one of the ingredients. NaCl is a well known preservative. There are a multitude of preservatives known in the prior art and the specification provides no guidelines as to which preservatives are excluded. Hence, one of ordinary skill in the art could not ascertain and interpret the metes and bounds of the patent protection desired as to the method of treatment encompassed by the recited phrase herein.

Claims 1 and 2 are further rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 refers to a "glucocorticoid." Glucocorticoids are defined by their activity to glucocorticoid receptors. Specification describes anecortave acetate as an angiostatic agent. (Page 8, lines 7-9). Anecortave acetate is reported to have only "little glucocorticoid" activity by Penn et. al. (Page 283, Column 2, Paragraph 2, lines 1-4, PTO-1449, Included by the applicant). Edelman et. al, reports that, "the anti-angiogenic steroid anecortave acetate binds to the glucocorticoid receptor in vitro and significantly inhibits VEGF-mediated retinal vascular leakage in vivo." (Abstract, Conclusions, PTO-892, Cited by the examiner).

Furthermore, there is a large class of molecules with glucocorticoidal activity. The term "glucocorticoid" is not clearly defined the specification and there are conflicting reports in the prior art regarding the glucocorticoidal activity of compounds, in particular anecortave acetate. Hence, one of ordinary skill in the art could not ascertain and interpret the metes and bounds of the patent protection desired as to the use of the term "glucocorticoid" herein.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 2 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of copending Application No. 10545055. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 2 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. 10545053 in view of Penn et. al. (PTO-1449, Included by the applicant).

The present application is directed towards the use of glucocorticoids and anecortave acetate for the treatment of nonproliferative diabetic retinopathy and retinal edema.

The '053 application is directed to the use of glucocorticoids and anecortave acetate for the treatment of pathologic ocular angiogenesis and any associated edema. The '053 application does not expressly claim the use of above-mentioned compounds for the treatment of retinal edema or nonproliferative diabetic retinopathy.

Penn et. al. shows that diabetic retinopathy is an angiogenic ocular condition. (Page 283, Column 1, Paragraph 1, lines 3-7).

It would have been obvious to one of ordinary skill in the art to use glucocorticoids, by itself, or in combination with anecortave acetate for the treatment of nonproliferative diabetic retinopathy and retinal edema.

This is a provisional obviousness-type double patenting rejection.

Claim 2 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10772963 in view of Penn et.al. (PTO-1449, Included by the applicant).

The '963 application is directed to the treatment of pathologic ocular angiogenesis and associated edema by the administration of compositions containing a glucocorticoid and anecortave acetate. The '963 patent does not expressly claim the treatment of nonproliferative diabetic retinopathy or retinal edema.

Claim 2 of the present application is directed to the use of anecortave acetate in combination with a glucocorticoid for the treatment of nonproliferative diabetic retinopathy and retinal edema.

As discussed above, Penn et. al. teaches that diabetic retinopathy is an angiogenic ocular condition. (Page 283, Column 1, Paragraph 1, lines 3-7). Nonprofilerative diabetic retinopathy is one of the two well known classes of diabetic retinopathies.

It would have been obvious to one of ordinary skill in the art to use glucocorticoids in combination with anecortave acetate for the treatment of nonproliferative diabetic retinopathy and retinal edema.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Martidis, A. et. al. (W, PTO-892, cited by the examiner). Martidis teaches the use of triamcinolone acetonide, a glucocorticoid, in patients with nonproliferative diabetic retinopathy. (Page 920, lines 1-2, Purpose, and Page 921, Table 1).

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Norden A, et. al. (V, PTO-892, cited by the examiner). Norden teaches the use of prednisolone

acetate, a glucocorticoid, for the treatment of retinal edema. (Page 234, Column 2, lines 21-25, and Page 235, Column 1, lines 6-9).

Claim 1 is further rejected under 35 U.S.C. 102(b) as being anticipated by Jonas et.al. (U, PTO-892, cited bye the examiner). Jonas teaches the use of cortisone, a glucocorticoid, for the treatment of nonproliferative diabetic retinopathy. (Page 426, Column 1, lines 1-3, and paragraph 2).

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark, AF. (U.S. Patent # 6,297,228, PTO-1449, Included by the applicant.). Clark teaches the use of angiostatic steroids, in particular anecortave acetate, for the treatment of any ocular neovascularization including diabetic retinopathy. (Column 4, Paragraph 3, lines 22-32). Nonproliferative diabetic retinopathy is one of the two well known diabetic retinopathies. (Merck Manual of Diagnostics, 12th edition, Page 2384, section "Diabetic Retinopathy," lines 4-7). Clark further teaches the use of anecortave acetate and the glucocorticoid tetrahydrocortisol for the prevention of ocular neovascularization. (Column 8, Claim1, lines 40-5). Claims 1 and 2 are rejected under 35 U.S.C § 102 (b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Penn et. al. (Form 1449, included by the applicant) in view of Jonas et. al (U, PTO-892, cited bye the examiner).

Penn et. al. teaches the use of angiostatic steroids, particularly anecortave acetate in an effective amount for the treatment of angiogenic ocular conditions, including diabetic retinopathy. (Page 283, Column 1, lines 3-11). Penn et. al shows the use of a 10% suspension of anecortave acetate. (Page 284, Column 2, lines 13-18). Nonproliferative diabetic retinopathy is one of the two well known diabetic retinopathies. (Merck Manual of Diagnostics, 12th edition, Page 2384, section "Diabetic Retinopathy," lines 4-7). Penn et. al. shows that anecortave acetate significantly inhibited pathologic retinal angiogenesis and that it holds therapeutic potential for a number of human ocular conditions in which angiogenesis plays a critical pathologic role. (Page 283, Column 1, Conclusions, lines 5-10). Diabetic retinopathy and specifically, nonproliferative diabetic retinopathy, are angiogenic ocular conditions.

Jonas teaches the use of cortisone, a glucocorticoid in an effective amount, for the treatment of nonproliferative diabetic retinopathy. (Page 426, Column 1, lines 1-3, and paragraph 2).

Penn et. al. and Jones et. al. does not expressly teach that the combination of a glucocorticoid and anecortave acetate is useful in a method to treat diabetic retinopathy or retinal edema.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ a glucocorticoid such as cortisone in combination with anecortave acetate for the treatment of nonproliferative diabetic retinopathy to optimize the effective amounts of active agents in the composition to be administered.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ a glucocorticoid such as cortisone with anecortave acetate for the treatment of nonproliferative diabetic retinopathy.

Therefore one of ordinary skill in the art would have reasonably expected that combining a glucocorticoid with anecortave acetate, both known useful for treating diabetic retinopathy, would improve the therapeutic effects for treating the same disease, and/or would produce additive therapeutic effects in treating the same.

It has been held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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April 28, 2006

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